

## REMARKS

This amendment is in response to the Office Action, dated March 24, 2010 ("Office Action"). Claims 17-28 remain pending. No new matter has been added.

### 35 U.S.C. §103(a)

Examiner rejected claims 17-28 under 35 U.S.C. §103(a) as being obvious over Fan, *et al.*, in view of Oka, *et al.* and Sharifi, *et al.*

First, Examiner asserts that Applicants' previously submitted Declaration of Prediman Shah is not sufficient to demonstrate that conception of the invention as claimed was completed prior to the publication of the Oka, *et al.* reference. Citing MPEP § 715, Examiner asserts that the Declaration of Prediman Shah is not sufficient because it did not include the signature of additional inventors Saswati Chatterjee and Kamehameha Wong. In response, Applicants submit that Examiner has misconstrued MPEP § 715 in terms of requiring all inventors to sign a 37 CFR 1.131 Declaration when demonstrating prior conception. Regardless, in the interest of expediting prosecution, although Applicants do not in any way concede that the 37 CFR 1.131 Declaration must be signed by all inventors to the claimed invention, Applicants submit the Declarations of Prediman Shah, Saswati Chatterjee and Kamehameha Wong enclosed herein as Exhibit A, B and C. Because conception of the invention as claimed was completed by Applicants prior to the publication of Oka, *et al.*, followed by diligent efforts by Applicants to reduce the invention to practice, Applicants submit that Fan, *et al.* in view of Oka, *et al.* does not render the claimed invention obvious.

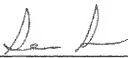
Second, Examiner asserts, even if the Oka, *et al.* reference is overcome, it remains that the claimed invention would be obvious over Fan, *et al.* in view of the abstract Sharifi, *et al.* Examiner asserts that Fan, *et al.* teaches the AAV-based delivery of human Apo A-I into the skeletal muscle for treatment of atherosclerosis, and Sharifi, *et al.* teaches AAV mediated Apo A-I Milano gene therapy for the treatment of atherosclerosis and restinosis. In response, Applicants submit that the abstract Sharifi, *et al.* does not teach AAV mediated Apo-A-I Milano gene therapy for treatment of atherosclerosis and restinosis. Rather than teaching Apo A-I Milano gene therapy for treatment as Examiner has asserted, Sharifi, *et al.* only describes the successful expression of the Apo A-I Milano gene. Sharifi, *et al.* notes in passing that previous experimental studies from their laboratory have documented some beneficial effects of

recombinant apo-A-I milano in atherosclerosis. However, the focus of Sharifi, *et al.* is to provide preliminary data demonstrating gene transcription in vivo. The Sharifi, *et al.* abstract does not describe what effect this expression will have on atherosclerosis or any disease for that matter, only that the AAV vector may express the Apo A-I Milano gene. Describing the expression of the Apo A-I Milano gene does not describe how, or even if, this expression will result in the successful treatment of atherosclerosis or restinosis. Due to the deficiencies in Sharifi, *et al.*, Fan, *et al.* in view of Sharifi, *et al.* does not render the claimed invention obvious.

In light of the aforementioned remarks and enclosed Declarations of Prediman Shah, Saswati Chatterjee and Kamehameha Wong, Applicants submit that the rejection of claims 17-28 under 35 U.S.C. §103(a) as being obvious over Fan, *et al.* in view of Oka, *et al.* and Sharifi, *et al.* should be withdrawn, as the cited references are not prior art.

All of the claims in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If for any reason Examiner finds the application other than in condition for allowance, Examiner is requested to call either of the undersigned attorneys at the Los Angeles telephone number (213) 633-6800 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,  
Prediman K. SHAH *et al.*  
DAVIS WRIGHT TREMAINE LLP

By:   
Sean D. Senn  
Registration No. 56,747

865 South Figueroa Street, Suite 2400  
Los Angeles, CA 90017-2566  
Phone: (213) 633-6800  
Facsimile: (213) 633-6899